PATENT

Docket No. 4007528/173387

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/Holly D. Kozlowski/

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**IN THE UNITED STATES PATENT & TRADEMARK OFFICE**

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| Applicant: | Sabine Stumvoll et al | : | Confirmation No.: 1495 |
| Serial No.: | 10/027,625 | : | Group Art Unit: 1644 |
| Filing Date: | December 21, 2001 | : | Examiner: Nora M. Rooney |

For: **Use of a Pure Allergen Component**

## APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The present Appeal Brief is submitted in support of the Notice of Appeal filed electronically on March 27, 2009.

## I. REAL PARTY IN INTEREST

The real party in interest for the present application is the Assignee of record, Phadia AB of Uppsala, Sweden.

## II. RELATED APPEALS AND INTERFERENCES

No prior or pending appeals, interferences or judicial proceedings are know to the Appellants, the Appellants' undersigned legal representative, or the Assignee which may be related to, directly affect or be directly affected by, or have a bearing on the Board's decision in the present appeal.

## III. STATUS OF THE CLAIMS

Claims 1-29 have been cancelled from the present application. Claims 30-36 are pending and stand rejected, and are the subject of the present appeal. A complete copy of the appealed claims is set forth in the Claims Appendix.

## IV. STATUS OF AMENDMENTS

No amendment was submitted subsequent to the final rejections set forth in the Official Action dated November 28, 2008.

## V. SUMMARY OF THE CLAIMED INVENTION

The present invention is directed to methods for serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic (see the specification at page 1, line 4 (Title) and lines 6-8; page 3, lines 2-8 and 19-20).

According to claim 30, the method comprises selecting an individual known to be weed pollen allergic, wherein it is not known if the individual is *Parietaria* allergic (see the specification at page 3, lines 2-8; page 3, line 25-page 4, line 6; page 4, lines 14-15; page 5, line 28); selecting a pure *Parietaria* allergen component known to have limited or no cross-reactivity (see the specification at page 3, lines 11-12 and 19); contacting serum from the selected individual with the pure allergen component (see the specification at page 5, lines 18-25), wherein the pure allergen component is pure Par j 1 or Par j 2 allergen component (see the specification at page 3, lines 19-20); determining the presence of IgE binding to said pure Par j 1 or Par j 2 allergen component (see the specification at page 5, lines 18-25); and identifying the individual as *Parietaria* allergic if the contacted serum contains IgE binding to said pure allergen component (see the specification at page 4, lines 6-11; page 7, lines 17-22).

According to claim 31, the method further comprises selecting an allergy treatment involving extract, proteins or peptides derived from a *Parietaria* species for an individual identified as *Parietaria* allergic (see the specification at page 3, lines 8-10 and 14-16).

Claim 32 recites the pure allergen component is Par j 1 while claim 33 recites the pure allergen component is Par j 2 (see the specification at page 3, lines 19-21).

Claim 34 recites the pure allergen component is recombinant, and claim 35 further specifies the pure allergen component of claim 34 is recombinant Par j 1 while claim 36 further specifies that the pure allergen component of claim 34 is recombinant Par j 2 (see the specification at page 3, lines 19-21).

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There are two grounds of rejection presented for review:

A. The rejection of claims 30-32, 34 and 35 under 35 U.S.C. §102(b) as being anticipated by EP 707 065 A2 (EP '065).

B. The rejection of claims 30, 33, 34 and 36 under 35 U.S.C. §103(a) as being obvious and unpatentable over EP '065 in view of Duro et al, *FEBS Letters*, 399:295-298 (1996) (Duro et al).

## VII. ARGUMENTS

As will be set forth in detail below, the methods defined by claims 30-32, 34 and 35 are not anticipated by EP '065 and are patentably distinguishable from EP '065. Moreover, the methods defined by claims 30, 33, 34 and 36 are nonobvious over and patentably distinguishable from EP '065 in view of Duro et al. Accordingly, the rejections should be reversed and favorable action by the Board is respectfully requested.

### A. Claims 30-32, 34 and 35 are Not Anticipated by EP '065

Claims 30-32, 34 and 35 are not anticipated by EP '065 and therefore, the rejection of these claims under 35 U.S.C. §102(b) should be reversed.

#### 1. The Examiner's Rejection

In rejecting claims 30-32, 34 and 35 under 35 U.S.C. §102(b), the Examiner asserted that EP '065 teaches a method for serologically identifying with improved accuracy an individual known to be weed pollen allergic (grass allergic) as *Parietaria* allergic by the steps of claim 30 using Par j 1. Specifically, the Examiner asserted that the claimed "individual known to be weed pollen allergic" is anticipated both by grass pollen allergic individuals shown in Example 8 and by the fact that the diagnostic method of EP '065 is directed toward diagnostic procedures for all individuals, as grass pollen individuals are a subset of all individuals which are encompassed by the teachings of the reference so a diagnostic procedure which identifies *Parietaria* allergic individuals from all individuals would inherently identify *Parietaria* allergic individuals from weed pollen allergic individuals (see the Official Action of November 28, 2008, pages 3-4).

#### 2. The Rejection Under 35 U.S.C. §102(b) Should be Reversed

The methods of claim 30, and claims 31, 32, 34 and 35 dependent on claim 30, are not anticipated by EP '065, whereby the rejection under 35 U.S.C. §102(b) should be reversed.

More particularly, as defined by claim 30, the invention is directed to a method for serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic, which method comprises selecting an individual known to be weed pollen allergic, wherein it is not known if the individual is *Parietaria* allergic, and selecting a pure *Parietaria* allergen component known to have limited or no cross-reactivity. The method further comprises contacting serum from the selected individual known to be weed pollen allergic with the selected pure allergen component, which is pure Par j 1 or Par j 2 allergen component, determining

the presence of IgE binding to said pure Par j 1 or Par j 2 allergen component; and identifying the individual as *Parietaria* allergic if the contacted serum contains IgE binding to said pure allergen component.

Thus, the present methods are for accurately identifying a *Parietaria* allergic individual, particularly when the individual is known to be generally weed pollen allergic but it is not known if the individual is *Parietaria* allergic. As described in the present specification, beginning at page 2, line 9, some allergens present in pollen of any particular weed species are represented by structurally similar homologues in other species and therefore show some degree of serological cross-reactivity, whereby sensitization to one weed species may lead to serological test positivity also to other species. Conventional serological testing using pollen extracts will in such cases generate ambiguous results in terms of identification of the actual sensitizer.

Appellants have determined that *Parietaria* pollen extract binds IgE from individuals not exposed to *Parietaria* pollen, while the recited pure allergen component Par j 1 or Par j 2 does not bind to IgE from such individuals. However, Par j 2 does bind IgE from most allergic individuals who are primarily sensitized to *Parietaria* pollen, as does Par j 1. Thus, Appellants have developed the present methods for specific identification of *Parietaria* allergic individuals from those known to be weed pollen allergic using a pure allergen component known to have limited or no cross-reactivity.

Attention is directed to the experimental work described in the present application, beginning at page 3, line 25, wherein the inventors establish that in a test group of patients from Austria (n=42), Scandinavia (n=8), the U.S. (n=18) and Italy (n=37), almost all patients contained IgE antibodies to ragweed, mugwort and *Parietaria* pollen extracts (i.e. not pure components). However, only a few Austrian (4) and no Scandinavian or American patients' sera had IgE that bound to Par j 2 (i.e. to the pure component). On the other hand, 81% of the Italian patients

contained IgE that bound to Par j 2. Typically, Mediterranean individuals are primarily sensitized to *Parietaria*. Accordingly, the present method is used to determine *Parietaria* allergic individuals.

EP '065 is cited in the Background portion of the present application and discloses recombinant *Parietaria* proteins and derived peptides. Particularly, EP '065 discusses conventional pollen extract immunotherapy and its disadvantages in the lack of standardized extracts, with variations in allergen content and non-allergen protein content (page 2, lines 39-53). EP '065 notes therefore that to eliminate some of the disadvantages of conventional allergenic preparations, research has been conducted to isolate and characterize the individual allergens of the complex repertoire of allergens of a given pollen (page 3, lines 2-4). EP '065 is specifically concerned with the cloning of the major allergens of the genus *Parietaria* (page 2, lines 5-6) and is directed toward the determination of DNA sequences coding for allergenic proteins of *Parietaria* plant pollens (page 3, lines 35-37).

However, EP '065 does not disclose or teach the use of a pure allergen component for accurately identifying a *Parietaria* allergic individual, particularly when the individual is known to be generally weed pollen allergic but it is not known if the individual is *Parietaria* allergic. Importantly, EP '065 does not teach the use of any of the proteins or peptides as reagents to distinguish between genuine *Parietaria* pollen sensitization and cross-reaction-mediated seropositivity to *Parietaria* pollen extract. In fact, in the "Immunoassay" discussion at page 7, lines 5-31, EP '065 discloses that a mixture of peptides may be used either as an immunogen in a composition or as a diagnostic agent, thereby demonstrating the EP '065 does not contemplate the use of a pure *Parietaria* allergen component, particularly a pure *Parietaria* allergen component known to have limited or no cross-reactivity, as compared with mixtures of *Parietaria* allergen components having cross-reactivity, to distinguish between general weed pollen allergy and *Parietaria* allergy.

The Examiner relied on Example 8 of EP '065 as anticipating the claim 30 limitation of "an individual known to be allergic." However, Example 8 does not disclose identification of an individual known to be weed pollen allergic as *Parietaria* allergic according to the limitations of present claim 30 and Example 8 does not indicate that a pure *Parietaria* allergen component known to have limited or no cross-reactivity is employed so that the presence of IgE identifies an individual as *Parietaria* allergic, rather than exhibiting cross-reactivity to one or more *Parietaria* allergens. To the contrary, EP '065 discloses that western blot analysis "**of *Parietaria* protein extracts**" (page 11, lines 55-56, emphasis added) was conducted. Thus, Example 8 employed extracts, not a pure allergen component. Additionally, EP '065 discloses that using "**pools of sera**" (page 11, line 56, emphasis added) from Italy (a pool of 13 sera) and Canada (a pool of 7 sera) showed that a 14 kDa component was recognized by both pools of sera. One of ordinary skill will appreciate that using pooled sera does not provide any diagnostic value relative to an individual. Thus, Example 8 of EP '065 does not anticipate the method of claim 30 of serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic. At best, Example 8 shows that each of the pools of sera from Italy and Canada contained IgE antibody which reacts with *Parietaria* extract. However, as shown in the experimental work in the present specification, IgE antibody which reacts with *Parietaria* extract is not determinative of *Parietaria* allergy.

In the final rejection, the Examiner also referenced Example 1 of EP '065 as anticipating the claimed method as *Parietaria* pollen extracts were separated and purified by SDS PAGE and Western blots were performed using serum from *Parietaria* pollen allergic individuals (page 6 of November 28, 2008 Official Action). However, Example 1 of EP '065 employed "**a pool of sera of 7 individuals** allergic to *Parietaria* pollen" (page 8, line 57, emphasis added). As in Example 8, one of ordinary skill will appreciate that using pooled sera does not provide any diagnostic value relative to an individual, and EP '065 provides no teaching or recognition in this regard. Moreover,

Example 1 provides no teaching or recognition of the limited or no cross reactivity of any of the separated proteins. One skilled in the art will appreciate that Example 1 of EP '065 is provided to show production and reactivity of murine polyclonal antibodies.

The Examiner asserted in the final rejection that "Knowledge of non-cross reactivity of Par j 1 is not necessary to anticipate the claimed invention" (page 6 of November 28, 2008 Official Action). Appellants respectfully disagree in that claim 30 is directed to serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic and requires the step of selecting a pure *Parietaria* allergen component known to have limited or no cross-reactivity. If a method is conducted without knowledge that the pure allergen component has limited or no cross-reactivity, there could be no identification of the individual as *Parietaria* allergic if the contacted serum contained IgE binding to the pure allergen component, and the limitations of claim 30 are not met.

The Examiner also asserted that it is well known that pooled serum is used for high throughput analysis and pooled serum which demonstrates a positive reaction is further screened (page 7 of November 28, 2008 Official Action). Not only are the Examiner's assertions completely unsupported by evidence of record, any such techniques are not disclosed by EP '065 which is the basis for the anticipation rejection. Examples 1 and 8 relied upon by the Examiner do not employ serum from a selected individual as recited in claim 30, but instead use pooled sera. Thus, the Examiner's assertions are irrelevant to the present rejection. Moreover, since EP '065 does not disclose that Par j 1, or any other allergen, has limited or no cross reactivity, even if such steps were conducted, there could be no identification of the individual as *Parietaria* allergic if the contacted serum contained IgE binding to the pure allergen component, and the limitations of claim 30 are not met.

The Examiner also asserted that even if the pooled serum could not be used to diagnose allergic individuals, the general teaching of the entire reference is directed to Par j 1 and its use for diagnosis of *Parietaria* pollen allergic individuals (page 7 of November 28, 2008 Official Action). However, the general teachings of EP '065 do not disclose each and every limitation of the method of claim 30, and the Examiner has relied on the specific teachings of Example 8 to assert that the specific limitations of claim 30 are inherent. That specific limitations of claim 30 are not inherent in Example 8 (or Example 1) cannot be ignored in an anticipation rejection by a mere reference to the general teachings of a reference. Further, contrary to the Examiner's assertion, nowhere does EP '065 specifically disclose a diagnostic method employing only Par j 1 with a serum sample from an individual. To the contrary, EP '065 generally discloses that the recombinant *Parietaria* allergens are useful in diagnosis and therapy of allergic diseases induced by *Parietaria* pollens (Abstract), without any attempt to account for cross reactivity with other pollens.

The Examiner cited *Atlas Powder Company v. IRECO*, 51 U.S.P.Q. 2d 1943 (Fed. Cir. 1999), as supporting the assertion that it is not necessary that those of ordinary skill in the art at the time of the invention knew that Par j 1 had limited or no cross-reactivity. However, the *Atlas Powder* case relates to inherent characteristics or functioning of a prior art **composition or ingredient** and does not provide any guidance regarding the inherency of a claimed **method**. Thus, the Atlas Powder case is not relevant to the present anticipation rejection.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In re Robertson*, 49 U.S.P.Q. 2d 1949, 1950 (Fed. Cir. 1999). To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill; inherency may not be established by probabilities or possibilities and the mere fact that a certain thing may

result from a given set of circumstances is not sufficient, *In re Robertson*, 49 U.S.P.Q. 2d at 1950-51. Similarly, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic, *In re Rijckaert*, 28 U.S.P.Q. 2d 1955, 1957 (Fed. Cir. 1993).

EP '065 fails to teach the use of a pure allergen component for serologically identifying an individual, particularly for serologically identifying an individual as *Parietaria* allergic, and EP '065 fails to teach or suggest selecting a pure allergen component known to have limited or no cross-reactivity. While the Examiner has asserted that the steps of the present methods are inherent in the teachings of EP '065, specifically that identifying *Parietaria* allergic individuals from all individuals will inherently identify *Parietaria* allergic individuals from weed pollen individuals, EP '065 does not provide any distinction between for an individual having antibodies binding to *Parietaria* extract versus an individual allergen. Further, the Examiner has not demonstrated any extrinsic evidence which makes clear that the missing elements are necessarily present in the EP '065 teachings, and that the claimed methods would be so recognized by persons of ordinary skill. To the contrary, the teachings of EP '065 relating to the use of a mixture of peptides for diagnostic use (page 7, lines 16-17) and the use of pooled sera (page 8, line 57 and page 11, lines 55-57) contradict the Examiner's assertions regarding inherency as no pure allergen component of known limited or no cross reactivity is employed and no individual is diagnosed using the pooled sera. Thus, EP '065 does not inherently describe the claim elements.

Accordingly, EP '065 does not expressly or inherently disclose each and every element of claim 30. Hence, EP '065 does not anticipate the present claims 30-32, 34 and 35 under 35 U.S.C. §102, whereby the rejection should be reversed.

**B. Claims 30, 33, 34 and 36 are Not Obvious over EP '065 and Duro et al**

Claims 30, 33, 34 and 36 are nonobvious over and patentably distinguishable from the combination of EP '065 in view of Duro et al, and, therefore, the rejection of these claims under 35 U.S.C. §103(a) should be reversed.

**1. The Examiner's Rejection**

In rejecting claims 30, 33, 34 and 36 under 35 U.S.C. §103(a), the Examiner relied on EP '065 for the various teachings employed in the rejection under 35 U.S.C. §102 set forth above. The Examiner relied on Duro et al as teaching a method of contacting serum with recombinant Par j 2 to detect pollen allergy, wherein Par j 2 is a new major allergen of *Parietaria judaica* pollen that reacts with the IgE of 82% of *Parietaria judaica* pollen sensitive patients. The Examiner asserted it would have been obvious to substitute Par j 2 of Duro et al for Par j 1 in a diagnostic method of EP '065 in view of the Duro et al teachings and a high rate of success would have been expected.

**2. The Rejection Under 35 U.S.C. §103(a) Should be Reversed**

The methods of claim 30, and claims 33, 34 and 36 dependent on claim 30, are nonobvious over and patentably distinguishable from the combination of EP '065 and Duro et al, whereby the rejection under 35 U.S.C. §103(a) should be reversed.

The method of claim 30, as well as the deficiencies of EP '065 with respect to the method of claim 30 are discussed in detail above and are incorporated herein in traversing the rejection under 35 U.S.C. §103(a). That is, EP '065 does not disclose or teach the use of a pure allergen component for accurately identifying a *Parietaria* allergic individual, particularly when the individual is known to be generally weed pollen allergic but it is not known if the individual is *Parietaria* allergic. Importantly, EP '065 does not teach the use of any of the proteins or peptides as reagents to distinguish between genuine *Parietaria* pollen sensitization and cross-reaction-mediated seropositivity to *Parietaria* pollen extract. In fact, in the "Immunoassay" discussion at page 7, lines

5-31, EP '065 discloses that a mixture of peptides may be used either as an immunogen in a composition or as a diagnostic agent, thereby demonstrating the EP '065 does not contemplate the use of a pure *Parietaria* allergen component, particularly a pure *Parietaria* allergen component known to have limited or no cross-reactivity, as compared with mixtures of *Parietaria* allergen components having cross-reactivity, to distinguish between general weed pollen allergy and *Parietaria* allergy.

The deficiencies of EP '065 are not resolved by Duro et al in that Duro et al similarly fail to teach a method for serologically identifying an individual known to be weed pollen allergic wherein it is not known if the individual is *Parietaria* allergic. That is, Duro et al are directed to a single allergen source, namely *Parietaria judaica* pollen, and do not mention other allergen sources or individuals known generally to be weed pollen allergic. While Duro et al seek to characterize one of at least 9 allergen components of this source, namely Par j 2, Duro et al are not concerned with any other allergy source. Further, by showing that 82% of the *Parietaria judaica* pollen sensitive patients' serum had IgE reacting with Par j 2, Duro et al merely show that Par j 2 is a major allergen (see page 297, right column, lines 18-21), and no other findings or conclusions are provided by Duro et al. Particularly, Duro et al do not teach or suggest that Par j 2, or any other pure allergen component, has limited or no cross reactivity and therefore can be employed in order to serologically identify with improved accuracy a *Parietaria* allergic individual from a general weed pollen allergic individual, as recited in present claim 30. In fact, while claim 30 recites the step of selecting an individual known to be weed pollen allergic, wherein it is not known if the individual is *Parietaria* allergic, Duro et al employ serum from individuals assertedly known to be *Parietaria* allergic. Further, while claim 30 requires selecting a pure *Parietaria* allergic component known to have limited or no cross-reactivity, Duro et al fail to teach, suggest or recognize that Par j 2 has limited or no cross-reactivity.

Importantly, Duro et al provide no teaching or suggestion that Par j 2 is a known pure allergen component with limited or no cross-reactivity. The previously submitted Declaration Under 37 C.F.R. 1.132 of the co-inventor Dr. Paolo Colombo confirms that the Duro et al paper does not disclose or suggest that the Par j 2 allergen has limited or no cross-reactivity with allergen components from other weed pollen allergen sources (paragraph 4) and thus does not teach or suggest using Par j 2, or any other purified allergen component, in methods for diagnosis of the actual sensitizing source from a variety of possible allergen sources (paragraph 4).

As in the anticipation rejection, the Examiner again asserted that whether or not individuals in the prior art were knowingly being serologically identified as *Parietaria* allergic is not necessary as the method is inherently identifying them (page 13 of November 28, 2008 Official Action). However, claim 30 is specifically directed to a method for identifying such an individual and particularly so identifying such an individual when the individual is known to be weed pollen allergic. If the prior art does not recognize the individual as identified as *Parietaria* allergic, as distinguished from weed pollen allergic, the prior art does not teach the claimed method. Moreover, as discussed in detail above, EP '065 teaches the use of pooled sera and therefore even if the Par j 2 of Duro et al were employed in place of Par j 1 in Examples 1 and/or 8 of EP '065, a method as recited in claim 30 would simply not result as no individual is identified.

Further, the Examiner asserted that Applicants' own specification and responses evidence that the *Parietaria* allergic individuals whose serum did not bind Par j 2 must inherently not be *Parietaria* allergic at all (page 13 of November 28, 2008 Official Action). However, the teachings of Applicants' specification and the descriptions of Applicants' invention in prosecution responses are not available as prior art to interpret what the Duro et al teachings would mean to one of ordinary skill in the art. As Duro et al still identify the individuals whose serum did not bind Par j 2 as *Parietaria* allergic, it is clear that Duro et al do not recognize or suggest the use of Par j 2 in a

method as recited in claim 30 for identifying *Parietaria* allergic individuals from weed pollen allergic individuals. To the contrary, Duro et al teach away from the presently claimed method in still identifying the individuals whose serum did not bind Par j 2 as *Parietaria* allergic. Hence, Duro et al do not resolve the deficiencies of EP '065.

Only in light of Applicants' specification can the Examiner conclude that the 18% of patients having serum which did not react with Par j 2 are inherently not allergic to *Parietaria judaica* and therefore must be allergic to another allergen from another weed pollen source while the 82% of patients having serum that reacts with Par j 2 are *Parietaria* allergic. Contrary to the Examiner's assertion that EP '065 and Duro et al need not teach or recognize that Par j 2 is of limited or no cross-reactivity, the step of selecting a pure *Parietaria* allergen component known to have limited or no cross-reactivity of claim 30 requires that EP '065 or Duro et al must provide this very teaching in order to anticipate the claimed method for serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic.

All words in a claim must be considered in judging the patentability of the claim against the prior art, *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970); MPEP 2143.03. In the present rejection, the Examiner has improperly disregarded several limitations of the method of claim 30 to conclude that the combination of EP '065 and Duro et al render claim 30 obvious. For example, in relying on EP '065's Examples 1 and 8 employing pooled sera, the Examiner has improperly disregarded the fact that an individual is identified in the method of claim 30 and has disregarded that fact that serum from the individual is contacted with the pure allergen component in the method of claim 30 to make the individual identification. Further, in concluding that it is not necessary to know the limited or no cross reactivity of Par j 1 or Par j 2, the Examiner has improperly disregarded the fact that claim 30 recites the step of selecting a pure *Parietaria* allergen component known to have limited or no cross-reactivity, and has improperly disregarded that fact that the known limited or no

cross-reactivity is necessary to make the identification required in the final step of claim 30. Accordingly, all words in claim 30 have not been considered in judging the patentability of claim 30.

As a result, the Examiner has not properly evaluated all of the differences between the invention as defined by claim 30 and the prior art of EP '065 and Duro et al as required by *Graham v. John Deere Co.*, 383 U.S. 1 (1966). Once the differences noted above are properly recognized, it is evident that the combination of EP '065 and Duro et al fails to render obvious a method for serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic, particularly an individual known to be weed pollen allergic, wherein it is not known if the individual is *Parietaria* allergic as recited in claim 30. Accordingly, EP '065 in view of Duro et al does not render present claims 30, 33, 34 and 36 obvious under 35 U.S.C. §103, whereby the rejection should be reversed.

## VIII. CONCLUSIONS

For the reasons set for the in detail above, claims 30-36 are neither anticipated by EP '065 nor rendered obvious over EP '065 in view of Duro et al, whereby the rejections under 35 U.S.C. §§102 and 103 should be reversed. Favorable action by the Board is respectfully requested.

Respectfully submitted,

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## CLAIMS APPENDIX

30. A method for serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic, comprising selecting an individual known to be weed pollen allergic, wherein it is not known if the individual is *Parietaria* allergic; selecting a pure *Parietaria* allergen component known to have limited or no cross-reactivity; contacting serum from the selected individual with the pure allergen component, wherein the pure allergen component is pure Par j 1 or Par j 2 allergen component; determining the presence of IgE binding to said pure Par j 1 or Par j 2 allergen component; and identifying the individual as *Parietaria* allergic if the contacted serum contains IgE binding to said pure allergen component.

31. The method according to claim 30, further comprising selecting an allergy treatment involving extract, proteins or peptides derived from a *Parietaria* species for an individual identified as *Parietaria* allergic.

32. The method according to claim 30, wherein the pure allergen component is Par j 1.

33. The method according to claim 30, wherein the pure allergen component is Par j 2.

34. The method according to claim 30, wherein the pure allergen component is recombinant.

35. The method according to claim 34, wherein the pure allergen component is recombinant Par j 1.

36. The method according to claim 34, wherein the pure allergen component is recombinant Par j 2.

## EVIDENCE APPENDIX

A copy of the Declaration Under 37 CFR 1.132 filed by facsimile on May 16, 2007 and entered by the Examiner (see the Official Action dated June 20, 2007, page 2, paragraph 2) is submitted herewith. There is no other evidence submitted pursuant to 37 C.F.R. §§ 1.130, 1.131, or 1.132 or otherwise entered by the Examiner relied upon herein by Appellants.

## RELATED PROCEEDINGS APPENDIX

There are no decisions from any related proceedings as described in Section II of the present Appeal Brief.